



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,317	10/12/2001	Alan David Watson	WATS3001/REF/C	8178

7590

05/01/2003

Richard E. Fichter  
BACON & THOMAS, PLLC  
Fourth Floor  
625 Slaters Lane  
Alexandria, VA 22314-1176

EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/01/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/975,317

Applicant(s)

WATSON ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. 0.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1616

***Response to Amendment***

The preliminary amendments filed 10/12/2001 and 01/07/2002 have been entered.

Consequently, the specification has been amended to insert the continuing data and the brief description of the drawings. Claims 1-30 have been canceled. New claims 31-50 have been added and are pending.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47-50 are confusing with the recitation of "subjecting said body to a magnetic resonance procedure as defined in claim 31" because the method of MRI in claim 31 already requires the administration of a contrast agent (e.g., the manganese complex), subjecting a body to MRI...and providing a series of images, and it is unclear if the steps of administering the contrast agent (manganese complex) and providing the series of images as recited in claims 47-50 are additional to those steps in base claim 31 or not. The recitation of the dependency "as defined in claim 31" brings in all the limitations (i.e., steps) of base claim 31, thus, it is unclear how this recitation of dependency limits claims 47-50, for example, by only incorporating a single step of the base claim (e.g., the imaging step) or all of the steps, (which would encompass two administration steps of the manganese complex and two steps of providing a series of images). The scope of the claims cannot be determined, since it is unclear how the dependency is limiting the claims, as dependency requires all the limitations of the base claims and additional limitations, which would suggest the two administration steps and two providing steps, as set forth above, but this does not seem to be the situation meant to be claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1616

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-33, 35-40 and 46-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Ericsson (WO 95/02831, US 5,869,023 used as a US equivalent).

Ericsson discloses a method of detecting myocardial ischemia in a subject comprising administering a physiologically acceptable manganese complex at a dosage within the claimed range (see column 7, lines 62-65) and subjecting the body to MRI (as claimed, i.e., echo planer) and providing a series of images to identify regions of abnormal blood flow (e.g., an infarction), see examples 4-6, which discloses various methods of imaging myocardial ischemia, as claimed, including determining the severity (column 6, lines 26-34), imaging reperfusion (example 6), etc. The contrast agents include manganese complexes, such as Mn-DTPA, as claimed, etc., see column 6, lines 50-65. Since the contrast agents disclosed by Ericsson are the same as encompassed by the instant invention, i.e., claim 46, such contrast agents (e.g., Mn-DTPA) would be expected to have the same properties as claimed, i.e.,  $K_a$  values. While the methods disclosed by Ericsson relate to the use of both a positive and negative contrast agent, the instant claims are open-ended, by reciting "comprising" and therefore do not exclude the use of additional contrast agents, as disclosed by Ericsson.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-33 and 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edelman (US Pat. 5,492,123) in view of Rocklage (US Pat. 4,889,931).

Edelman discloses a method of detecting myocardial ischemia in a body comprising administering a contrast agent and subjecting the body to MRI to identify regions of abnormal blood flow

Art Unit: 1616

to detect the ischemia, see column 1 and column 2, lines 25-36. Various MRI methods may be employed, such as echo planar MRI, etc., which would encompass the MRI methods and conditions thereof, as instantly claimed, see columns 1-2 and column 5, lines 37+. Edelman teaches that contrast agents are employed, such as, a Gd-DTPA metal complex, see column 5, lines 32-36.

Edelman fails to disclose the use of the same contrast agents as instantly claimed (e.g., manganese complexes, such as, those of formula I and dosages thereof.

Rocklage discloses MRI contrast agents comprising manganese are superior chelating agents which are highly stable, making them very suitable for methods of MRI imaging, see column 1. Thus, Rocklage teaches that manganese is the preferred metal for such MRI complexes. The contrast agents include manganese complexes of DTPA, DPDP, etc. is especially preferred, see column 4, lines 50+. These chelates are the same as those instantly claimed and are used in dosages which encompass those instantly claimed, see column 9, lines 1+. Since these contrast agents are the same as those instantly claimed, they would be expected to have the same functional characteristics and properties as instantly claimed.

It would have been obvious to one of ordinary skill in the art to modify the methods disclosed by Edelman to use a manganese contrast agent and dosages thereof, as instantly claimed, because such Rocklage teaches that such contrast agents (e.g., a manganese complex of DPDP, DTPA, etc.) are superior chelating agents which are highly stable, thus, making them very suitable for methods of MRI imaging when used in dosages encompassed by the claims. One of ordinary skill in the art would have been motivated to employ the improved manganese complexes as the contrast agents in the methods of Edelman to gain the advantages Mn complexes, including optimum MRI properties, decreased toxicity, etc., as is known in the art, as shown by Rocklage.

Claims 31-33, 35-40 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edelman (US Pat. 5,492,123) in view of Ericsson (WO 95/02831, US 5,869,023 used as a US equivalent).

Art Unit: 1616

Edelman discloses a method of detecting myocardial ischemia using a metal chelate and MRI as set forth above.

Edelman fails to specifically disclose the use of manganese as the metal in the chelate and the various modifications of detecting such conditions as set forth in claims 47-50.

Ericsson discloses a method of detecting myocardial ischemia in a subject, as set forth above. Ericsson teaches that Mn is an equivalent metal to Gd (as disclosed by Edelman) and that the methods may be employed for various evaluations of myocardial ischemia, including evaluating severity, reperfusion, injured tissue, etc, see column 6, lines 50-65 and examples 4-6.

It would have been obvious to one of ordinary skill in the art to have used Mn instead of Gd in the DTPA metal complex used in the methods disclosed by Edelman because it is well known in the art that Mn is an equivalent metal to form a complex with DTPA for methods of MRI, as shown by Ericsson. Also, it would have been obvious to one of ordinary skill in the art to employ the methods disclosed by Edelman for various myocardial diagnostic determinations because Edelman teaches general methods of myocardial imaging and methods to identify various subgroups thereof, severity, etc., (as claimed) are well within such general methods and/or are known in the art as shown by Ericsson.

Claim 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Edelman (US Pat. 5,492,123) in view of Rocklage (US Pat. 4,933,456), as applied to claims 31-33 and 35-46 above, in further view of Goldenberg (US Pat. 5,632,968).

Edelman fails to specifically disclose that the echo imaging is an inversion recovery echo imaging method.

Goldenberg discloses methods of imaging cardiovascular lesions and teaches that inversion recovery is a well known and equivalent method of spin-echo MRI, see column 13, lines 23-48.

It would have been obvious to one of ordinary skill in the art to further modify the methods disclosed by Edelman to use inversion-recovery spin-echo MRI as the spin echo MRI procedure because it is well known in the art that this is a useful and equivalent method of spin-echo MRI as taught by Goldenberg.

Art Unit: 1616

Claim 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Ericsson in view of Goldenberg (US Pat. 5,632,968).

Ericsson while disclosing that various known echo imaging MRI modalities may be employed fails to specifically disclose that the echo imaging is an inversion recovery echo imaging method.

Goldenberg discloses methods of imaging cardiovascular lesions and teaches that inversion recovery is a well known and equivalent method of spin-echo MRI, see column 13, lines 23-48.

It would have been obvious to one of ordinary skill in the art to further modify the methods disclosed by Ericsson to use inversion-recovery spin-echo MRI as the spin echo MRI procedure because it is well known in the art that this is a useful and equivalent method of spin-echo MRI as taught by Goldenberg.

#### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.


#### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
April 30, 2003